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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,160	11/01/2001	Ronald Alan Coffee	13401	2938

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
02/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/018,160	COFFEE ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,7-9,11,13-15,35,36,40-42,59,60,71-94 and 96-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4, 7-9, 11, 13-15, 35-36, 40-42, 59-60, 71-94 and 96-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Request for Continued Examination and Amendments filed on 11/23/2009.

- Claims 4, 14, 73 and 74 have been amended.
- Claims 1-3, 5-6, 10, 12, 16-34, 37-39, 43-58, 61-70 and 95 have been cancelled.
- Claims 4, 7-9, 11, 13-15, 35-36, 40-42, 59-60, 71-94 and 96-98 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/23/2009 has been entered.

Response to Declaration under C.F.R. § 1.132

Applicant's Declaration of Michael D. Triplett submitted under 37 C.F.R. 1.132 filed on 11/23/2009 has been received and entered into the application.

The declaration submitted by Michael Triplett assert that the broad invention claimed by the instant application is a method of preparing a rapidly dissolving tablet that is formed using electric field technology (electrohydrodynamic). And the Coffee

reference refers to "controlled release" product by using polyhydroxybutyric acid, polyvinyl alcohol and polyurethane polymers which are known to be useful in the preparation of controlled release pharmaceutical products. In the present case, the instantly claimed invention is drawn to solid forms manufactured by electrodynamic process comprising an active agent and gelatin. The same is broadly disclosed by the prior art. In one embodiment, the polyvinyl alcohol having a molecular weight in the range of about 90,000 to 140,000 will tend to form fibrils and therefore, it assumed that the instantly claimed invention and the prior art both share the property of being able to melt, liquefy, disintegrate or dissolve on specific moist tissue surfaces in specific time. The mere recitation of this property or future intended use does not, on its own, add anything further to the instantly claimed invention in terms of physical structure of the instantly claimed or recited compositions, nor does it add anything further to the instantly claimed invention in terms of specific ingredients in specific quantities that impart the recited function that would have been unobvious in view of the prior art.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 7-9, 11, 13-15, 35-36, 40-42 and 59-60 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 4 recite the newly amended limitation of "liquid consists essentially of a gelatin, polyvinyl pyrrolidone, polyvinyl alcohol having a molecular weight of from about 100,000 to about 130,000, vinylpyrrolidone/vinylacetate copolymer, and vinylpyrrolidone/vinylimidazole copolymer", however, the specification as filled does not provide a written description or set forth the metes and bounds of this phrase. The recitation of above polymers was not shown in single formulation rather it includes one single polymer for individual formulation. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, introduce new concepts and thus violate the written description requirement of the first paragraph of 35 U.S.C. §112.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to identify sufficient written support in the original specification for the "limitations" indicated above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 7-9, 11, 13-15, 35-36, 40-42, 59-60, 71-94 and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "rapidly and completely dissolve on moist surfaces" is a relative term which renders the claims indefinite. The term "rapidly and completely dissolve on moist surfaces" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of disintegration or release of active ingredient in certain time period, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. What time period constitutes rapidly and completely dissolve on what type of moist surfaces. Therefore, one would not know what the metes and bounds of the claims are.

Further, claim 96, recites liquid consists of a solution of a biologically acceptable, hydrophilic polymer (single) dissolved in a solvent for said polymer, and claims 4 recites wherein said liquid consists essentially of a gelatin, polyvinyl pyrrolidone, polyvinyl alcohol having a molecular weight of from about 100,000 to about 130,000, vinylpyrrolidone/vinylacetate copolymer, and vinylpyrrolidone/vinylimidazole copolymer (which includes five different polymers in formulation). The combination of five different polymers is not defined in the specification. An ordinary skill in the art would not be appraised of the metes and bounds of what constitutes the biologically acceptable hydrophilic polymer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4, 7-9, 11, 13-16, 35-36, 40-42, 59-60, 71-94 and 96-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee (W0-98/03267) in view of Liu et al (US 6,465,009) and Murray et al (US 6,709,669) **are withdrawn** in view Amendment to claims.

However, upon further consideration a new ground(s) of rejection is prepared as follow.

Claims 4, 7-9, 11, 13-15, 35-36, 40-42, 59-60, 71-94 and 96-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee (WO-98/03267) in view of Barabas (US 4,704,436), Liu et al (US 6,465,009) and Murray et al (US 6,709,669).

Applicant claims are drawn to method of manufacturing a biodissolvable tablet containing one or more active medicaments.

Coffee teaches a processes and apparatuses for forming material by electrohydrodynamic comminution (Abstract; and page 4, lines 1-4). In one aspect, the processes and apparatuses disclosed within the document is capable of producing various solid and partially solid forms, such as fibers, fiber segments, fibrils, droplets, particles, webs, and mats. This formed matter may also contain a biologically active ingredient (page 2, line 12 to Page 3, Line 15). Fibers, fiber fragments, and particles of biologically active components for topical application such as analgesics, agents such as proteolytic enzymes, vaccines, and biological material, such as fibrin of collagen may also be formed using the processes and apparatuses (page 5, lines 29-35 and 6, lines 13-18). Alternatively, the active ingredient may be provided as a coating or core of the fibers, fibrils, or particles or microcapsules (page 5, lines 7-28). The solvents suitable for formation of fibres include alcohols such as methanol, propanol and water (page 19 lines 6-10). Active ingredients may be supplied onto fibers, fibrils, or droplets in the form or a liquid that is dispensed through an outlet nozzle (page 22, lines 23- 33). The reference discloses that fibers have been successfully spun with polyhydroxybutyric acid and polyvinyl alcohol, a water-soluble polymer (page 19, lines 20-23). The polyvinyl alcohol having a molecular weight in the region of about 90,000 to 140,000 is used in the formation of fibrils (page 20, lines 23-24). In the formation of material provided by the methods and apparatuses disclosed in the reference, the supply of the material may be assisted by an air or inert gas flow (claim 32; and page 30, lines 27-

31). When a melt is used as the material to be formed by the apparatuses and processes disclosed in the reference, the temperature of this material may be controlled by quenching using a cold air or inert gas stream (page 11, lines 17-22). Additional disclosure includes that the permeability and/or thickness of the coating may be adjusted to adjust the timing of release of the active ingredient for a specific formulation (pate 30 lines 16-24).

Note, thought the prior art is silent with respect to a cutting step in the disclosed method of production, as the prior art has disclosed the manufacture of particles in addition to fibers and mats, it is the view of the examiner that the use of a cutting step is would be within the level of skill of one of ordinary skill in the art.

Coffee fails to teach vinylpyrrolidone/vinylacetate copolymer, vinylpyrrolidone/vinylimidazole copolymer, fish gelatin and flavoring agent in the process of manufacturing microcapsules.

Liu teaches formulation and method of manufacture of tablets comprising pharmaceutically active ingredient such as medicament, drug, vitamins, and other pharmaceutical, nutritional and dietary agents reads on confectionary material (col. 8 lines 3-15), and at least one water soluble non-saccharide polymer such as polyvinylpyrrolidone (col. 2 lines 12-14). The tablets disintegrates rapidly or dissolves in about 1 to about 40 seconds in an aqueous solution, the tablet dissolves in the oral cavity and the aqueous solution is saliva (abstract and col. 2 lines 45-48). The polyvinylpyrrolidone can be vinylpyrrolidone-vinyl acetate copolymer (col. 2 lines 18-22). The tablet formulation comprises water soluble polymers such as polyethylene glycol,

gelatin, cellulose derivatives, saccharides or a mixture thereof (col. 6 lines 1-20), disintegrants includes sodium starch glycolate, crossarmellose sodium and the like and sweetening agents (col. 8). Additional disclosure includes that tablet, when placed in the body cavity, rapidly disintegrates without the need for any co-application or ingestion of fluid.

Barabas teaches a process for the production of ibuprofen complexes with the vinylpyrrolidone copolymer (col. 1 line 21-24). The vinylpyrrolidone copolymer contains an N-vinyl-2-pyrrolidone monomer and a commoner selected from the group of a di lower alkyl amino lower alkyl styrene, e.g. N-vinyl imidazole (col. 2 lines 23-29). Additional disclosure includes that ibuprofen complexed in this manner exhibits at least a 50 fold increase in water solubility over the uncomplexed compound (col. 2 lines 42-45).

Murray teaches a process for preparing fast-disintegrating dosage form comprising a carrier and an active ingredient (e.g. drug) wherein the carrier is fish gelatin and fast-dispersing dosage form releases the active ingredient rapidly on contact with a fluid (e.g., saliva, bodily fluids, water). Preferably, the composition is designed for oral administration (any other equivalent dosage form) and releases the active ingredient rapidly in the oral cavity (abstract and col. 3 lines 29- 40). The composition also contain, in addition to the active ingredient and fish gelatin carrier, other matrix forming agents such as polysaccharides, synthetic polymers such as polyvinylpyrrolidone,(col. 5 lines 24-40). The composition also includes flavoring agents such as mint reads on peppermint caramel, grape flavors and combinations thereof (col.

5 lines 63-65). Additional disclosure includes that the composition can be contained in a mold during the freeze-drying process to produce a solid form in any desired shape.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate water soluble polymer such as vinylpyrrolidone-vinyl acetate copolymer and fish gelatin into Coffee's method. The person of ordinary skill in the art would have been motivated to make those modifications, because vinylpyrrolidone-vinyl acetate copolymer and fish gelatin would assist in producing tablets with a better resistance to moisture and have adequate hardness, and reasonable would have expected success because both Liu and Murray teaches the formulation and method of manufacture of compressed tablets that is hard, and resistant to breakage during handling and release the active ingredient rapidly upon contact with body fluid or other aqueous medium.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate water soluble polymer such as vinylpyrrolidone/vinylimidazole copolymer into Coffee's method. The person of ordinary skill in the art would have been motivated to make those modifications, because vinylpyrrolidone/vinylimidazole copolymer would assist in producing tablets with a better resistance to moisture and have adequate hardness, and reasonable would have expected success because Barabas teaches that complexation of active ingredient with vinylpyrrolidone/vinylimidazole copolymer exhibits at least a 50 fold increase in water solubility over the uncomplexed compound and retains the properties associated with drug compound.

Claim limitations containing specific amounts of specific ingredients are considered by the examiner to be attainable by one of ordinary skill in the art through routine experimentation and are not considered to be critical. The amount of a specific ingredient and particle size in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results of drug release. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention. Claims limitations, reciting specific moist tissue surfaces are considered by the examiner to be recitations of intended use, and thus do not carry patentable weight.

Response to Arguments

Applicant's arguments filed on 11/23/2009 have been fully considered but they are not persuasive.

Applicant asserts that the Coffee reference standing alone, fails to render the presently claimed invention obvious within the meaning of 103(a) rejection; further, one skilled in this art would not have combined the teachings of Coffee within the teachings of Liu and Murray because the Coffee reference fails to provide any direction of teaching that would lead the skilled artisan to the preparation of a rapid-release tablet.

This argument is not persuasive because any statement of intended use, whether it is found in the preamble or any other part of a claim, does not render patentability unto that claim, unless it necessarily results in a physical or structural difference that is not obvious in view of the prior art. In the present case, the instantly claimed invention is drawn to solid forms manufactured by electrodynamic process comprising an active agent and gelatin. The same is broadly disclosed by the prior art. In one embodiment, the polyvinyl alcohol having a molecular weight in the range of about 90,000 to 140,000 will tend to form fibrils and therefore, it assumed that the instantly claimed invention and the prior art both share the property of being able to melt, liquefy, disintegrate or dissolve on specific moist tissue surfaces in specific time. The mere recitation of this property or future intended use does not, on its own, add anything further to the instantly claimed invention in terms of physical structure of the instantly claimed or recited compositions, nor does it add anything further to the instantly claimed invention in terms of specific ingredients in specific quantities that impart the recited function that would have been unobvious in view of the prior art. Therefore, the art rejection of record will be maintained.

With respect to Liu and Murray references, these references are combined for its teachings of knowledge in the art of employing vinylpyrrolidone-vinyl acetate copolymer and fish gelatin to assist in producing tablets with a better resistance to moisture.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr

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